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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,671	12/28/2000	David A. Zarling	A-68767-1/RFT/RMS/BTC	9120

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,671	ZARLING ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restrictions

1. Applicant's election of Group II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's cancellation of Claims 1-8 in Paper No. 7 is acknowledged.

Claims 9-16 are pending.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The provisional application upon which priority is claimed provides adequate support under 35 U.S.C. 112 for claims 9-16 of this application.

Information Disclosure Statement

3. The references listed on the 1449 received 31 January 2002 in Paper No. 5 have been reviewed and considered. Additionally, the International Search Report submitted in Paper No. 5 has been reviewed.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 9-16 are indefinite in Claim 9 for the recitation "detecting the presence of said assay complex" because it is unclear whether the complex or merely the presence of the complex is detected. It is suggested that Claim 9 be amended to clarify e.g. recite method steps of labeling and label detection (pages 7-8).

b. Claims 9-16 are indefinite in Claim 9 for the recitation "detecting the presence of said assay complex as an indication of the presence of said target sequence" because "indication of the presence" is a non-specific relational phrase. Therefore the relationship between detecting the assay complex and the target sequence is undefined. It is suggested that Claim 9 be amended to clarify e.g. replace "as an indication of the presence of" with "to detect".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international

application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 9, 10 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Drmanac et al (U.S. Patent No. 6,383,742 B1, filed 15 August 1997).

Regarding Claim 9, Drmanac discloses a method of detecting the presence of a target sequence in a sample comprising: providing a substrate comprising an array of capture probes; contacting said target sequence with said array wherein either said capture probes or said target sequences is coated with a recombinase to form an assay complex; and detecting the presence of said assay complex as an indication of the presence of said target sequence (Column 9, lines 16-45). The array of Drmanac is contacted with target sequence in the presence of recA protein "to permit hybridization". While Drmanac does not specifically state that either the capture probe or target sequences is coated with recA, based on the inherent property of recA-nucleic acid binding, the capture probe or the target sequence would inherently be coated recA.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding Claim 10, Drmanac discloses the method wherein the recombinase is recA (Column 9, lines 22-27).

Regarding Claim 12, Drmanac discloses the method wherein the capture probe comprises said recombinase (Column 9, lines 16-45) i.e. the complex comprising the capture

probe and target sequence comprises recA. Because the complex comprises recA, the capture probe which is a part of the complex also comprises recA.

Regarding Claim 13, Drmanac discloses the method wherein the target sequence comprises said recombinase (Column 9, lines 16-45) i.e. the complex comprising the capture probe and target sequence comprises recA. Because the complex comprises recA, the target sequence which is a part of the complex also comprises recA.

Regarding Claim 14, Drmanac discloses the method further comprises coating said target sequence with said recombinase (Column 9, lines 22-27) i.e. hybridization in the presence of recA inherently coats the target sequence with recombinase.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigawa et al (WO 98/08975, published 5 March 1998) in view of Drmanac et al (U.S. Patent No. 6,383,742 B1, filed 15 August 1997).

Regarding Claim 9, Kigawa et al teach a method of detecting the presence of a target sequence in a sample comprising: providing a substrate; contacting said target sequence with target sequences wherein either said capture probes or said target sequences is coated with a recombinase to form an assay complex; and detecting the presence of said assay complex as an

indication of the presence of said target sequence (page 17, line 20-page 18, line 3 and Claim 18). Additionally, Kigawa et al provide a substrate to which the probe-target complex is captured (page 17, lines 26-27) but they do not capture prior to probe-target complex formation. Drmanac teaches a similar method comprising: providing a substrate comprising an array of capture probes; contacting said target sequence with said array wherein either said capture probes or said target sequences is coated with a recombinase to form an assay complex; and detecting the presence of said assay complex as an indication of the presence of said target sequence (Column 9, lines 16-45) wherein their array of capture probes provides for detection of thousands of targets simultaneously (Column 6, lines 17-21). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the array of capture probes of Drmanac and to array the capture probes of Kigawa et al onto a support to thereby detect thousands of target sequences simultaneously as taught by Drmanac (Column 6, lines 17-21) for the obvious benefits of economy of time and labor. Alternatively, absence unexpected results, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Kigawa et al by immobilizing their capture probes onto the support prior to contact with the target sequence. One skilled in the art would have been motivated to array capture probes onto a support to thereby provide a reusable array of capture probes for the obvious benefit of economy of reusable components.

The courts have stated that wherein the process steps are known, absent unexpected results, the rearrangement of the process steps is prima facie obvious (see *In re Burhans* 154, F.2d 690, 69 USPQ 330 (CCPA 1946).

Regarding Claim 10, Kigawa et al teach the method wherein the recombinase is recA (page 17, lines 20-27 and Claim 28).

Regarding Claim 11, Kigawa et al teach the method wherein the recA is *E.coli* recA (page 14, lines 8-12 and Claim 28).

Regarding Claim 12, Kigawa et al teach the method wherein the capture probe comprises said recombinase (page 17, lines 20-24 and Claim 18).

Regarding Claim 13, Kigawa et al teach the method wherein the target sequence comprises said recombinase (page 17, lines 20-27 and Claim 18) i.e. the complex comprising the capture probe and target sequence comprises recA. Because the complex comprises recA, the target sequence which is a part of the complex also comprises recA.

Regarding Claim 14, Kigawa et al teach the method further comprises coating said target sequence with said recombinase (page 17, lines 20-24) i.e. hybridization in the presence of recA inherently coats the target sequence with recombinase.

Regarding Claim 15, Kigawa et al teach the method wherein the target sequence is RNA (page 11, lines 1-3 and Claim 18).

Regarding Claim 16, Kigawa et al teach the method wherein the RNA is coated with a recombinase (Claim 18) i.e. hybridization in the presence of recA inherently coats the target sequence with recombinase.

11. Claims 11, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al (U.S. Patent No. 6,383,742 B1, filed 15 August 1997) in view of Kigawa et al (WO 98/08975, published 5 March 1998).

Regarding Claim 11, Drmanac teaches the method of detecting the presence of a target sequence in a sample comprising: providing a substrate comprising an array of capture probes; contacting said target sequence with said array wherein either said capture probes or said target sequences is coated with a recombinase to form an assay complex; and detecting the presence of said assay complex as an indication of the presence of said target sequence

(Column 9, lines 16-45) but they do not specifically teach the recA is *E.coli* recA. However, *E.coli* recA was well known in the art at the time the claimed invention was made as taught by Kigawa et al who teach that *E.coli* recA is a recombinase which is bound to nucleic acid using well known techniques (page 14, lines 8-12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the *E.coli* recA to the recA of Drmanac based on the known techniques for attaching the *E.coli* recA to nucleic acids as taught by Kigawa et al (page 14, lines 8-12) for the obvious benefits of using well known techniques e.g. confidence of success.

Regarding Claims 15 and 16, Drmanac teaches the method comprising coating said target sequence with said recombinase (Column 9, lines 22-27) i.e. hybridization in the presence of recA inherently coats the target sequence with recombinase but they do not specifically teach the target sequence is RNA. However, RNA target sequences were well known and routinely practiced in the art as taught by Kigawa et al (page 11, lines 1-3 and Claim 18). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the RNA targets of Kigawa et al to the nucleic acid target detection of Drmanac to thereby detect RNA targets for the benefits of detecting expression-specific targets.

Prior Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Radding et al (U.S. Patent No. 4,888,274, issued 19 December 1989) teach a method for detecting the presence of a target sequence wherein either a capture probe or target sequence is coated with recombinase (Claims 1-14).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 3, 2002